REMARKS

Upon entry of this Amendment, claims 34, 36-44 will be pending. Claims 1-33, 45-46 and 48-49 were previously cancelled. Claims 35, 47 and 50-51 have been cancelled. Claim 34 has been amended as suggested by the Examiner. No new matter has been added. Applicants respectfully request the amendments be entered.

In this regard, amendment and cancellation of claims during pendency of the application are not to be construed as acquiescence to any of the objections and/or rejections set forth in any Office Action, and were made solely to advance prosecution and not to overcome any art of record, whether considered alone or in combination. Applicants reserve the right to pursue any subject matter originally filed and/or subsequently cancelled or deleted in this or future applications.

I. Concurrent Submissions

Concurrently submitted with this amendment are a declarations of Drs. Benny Bang-Andersen, Klaus Peter Bøgesø, and Klaus Gjervig Jensen, under 37 C.F.R. §1.132, and an Information Disclosure Statement (IDS). With the submission of this IDS, all documents cited in the declaration of Klaus Peter Bøgesø are believed to be of record in the application.

II. Claims' Objections

A. Claim 34

The United States Patent and Trademark Office ("the Office") objected to claim 34 because of the claim language, "a name" and suggests that better claim language is "the name". The claim has been amended as suggested. Consequently, the objection is moot and Applicants respectfully request the objection be withdrawn.

B. Claims 36 and 47

The Office has objected to claims 36 and 47 for allegedly being substantial duplicates. Claim 47 has been cancelled. Consequently, the objection is moot and Applicants respectfully request the objection be withdrawn.

III. Claims' Rejections

A. Claims 50-51

Claims 50-51 have been rejected under 35 U.S.C. 112(1) for allegedly failing to have descriptive support in the specification as originally filed. The rejection is moot since the claims have been cancelled. Applicants therefore respectfully request that the rejection be withdrawn.

B. Claim 34 is novel

The Office maintains its rejection of claim 34 under 35 USC §102(b) for allegedly being anticipated by Bøgesø et al., *J. Med. Chem.* 1995, 38:4380-92 ("the Bøgesø article"). Applicants traverse the rejection and respectfully request it be withdrawn.

Applicants maintain that the Bøgesø article does not anticipate *trans*-1-((1R,3S)-6-chloro-3-phenylindan-1-yl)-3,3-dimethylpiperazine of amended claim 1 for reasons of record.

Further, the Bøgesø article fails to teach the enantiomer of amended claim 34. Amended claim 34 recites in relevant part: "[a] compound having a name of trans-1-((1R,3S)-6-chloro-3-phenylindan-1-yl)-3,3-dimethylpiperazine…wherein the compound is stereochemically pure". The Bøgesø article clearly does not teach each and every aspect of amended claim 34. Claim 34, therefore, is novel. Accordingly, Applicants request the §102(b) rejection be withdrawn.

C. Claims are not obvious

The Office maintains its rejection of claims 34-44 and 47, and rejects claims 50-51 under 35 USC §103(a) for allegedly being obvious over the by the Bøgesø article and EP 0 638 073 ("the Bøgesø EP patent") ("the Bøgesø references"). Applicants traverse the rejection and respectfully request it be withdrawn.

Applicants maintain that the Bøgesø references do not make obvious *trans*-1-((1R,3S)-6-chloro-3-phenylindan-1-yl)-3,3-dimethylpiperazine ("Compound I") of amended claim 34 and dependent claims 36-44 for reasons of record. Again, amended claim 34 recites in relevant part: "[a] compound having a name of trans-1-((1R,3S)-6-chloro-3-phenylindan-1-yl)-3,3-dimethylpiperazine…wherein the compound is stereochemically pure."

Also, the Bøgesø references do not enable one of ordinary skill in the art to obtain stereochemically pure Compound I and certainly not with a reasonable expectation of success if one of ordinary skill in the art attempted to resolve its racemate. Even if one ordinarily skilled in the art was motivated to obtain Compound I by the generic disclosure of the Bøgesø EP patent as to the racemate of Compound I being a "preferred" compound, which Applicants do not concede

is a fair reading of it, it fails alone or combined with the Bøgesø article to provide s/he the requisite reasonable likelihood of success.

As put forth in the declaration of Klaus Peter Bøgesø ("the Bøgesø Declaration"), the Bøgesø references do not provide guidance to one ordinarily skilled in the art so as to reasonably expect s/he could successfully obtain Compound I if attempted. *See e.g.,* paragraphs 9-42. In fact, the disclosure of each Bøgesø reference is simply too general as to a resolution method to provide meaningful guidance that would lead one of ordinary skill in the art to the Compound I.

The diastereomeric salt formation resolution techniques taught by the Bøgesø article for resolving *trans* isomers of similar structure to Compound I are not taught or suggested by it as being able to resolve the racemate of Compound I with a reasonable expectation of success because the article indirectly discloses this racemate and the mere disclosure of the racemate and a resolution technique for compounds of similar structure does not mean that the racemate will be amendable to the resolution technique. *See, e.g.,* the Bøgesø Declaration at 10-15. In fact, Applicants' attempt to do so was unsuccessful. *Id.* at 16-22. Meanwhile, the disclosure of the Bøgesø EP patent with respect to resolution techniques is a mere suggestion that could result in undue experimentation. And in fact, this was the case of the Applicants. *Id.* at 23-39. While attempting to find a way to resolve the racemate of Compound I, it was not until Applicants found that a technique using chiral chromatography could for the first time successfully provide claimed Compound I, as disclosed in the present application, was this achieved. *Id.* at 40.

Moreover, Applicants maintain that Compound I has surprising and unexpected properties compared to the prior art compounds, and thus, is not obvious. With respect to the Office's concern with the test results in support of unexpected results submitted with Dr. Bang-Andersen's 11/13/08 declaration – namely affect on variability of the test results when comparing them over time (years), Applicants kindly direct the Office to the declaration of Dr. Gjervig Jensen, as well as the contemporaneously submitted declaration of Dr. Bang-Andersen and paragraph 41 of the Bøgesø Declaration. These declarations clearly evidence that the variability of the test results is not impacted by the fact that the results were obtained on different test dates. Consequently, as previously presented, Compound I has an unexpected and surprising property that is unpredictable and advantageous and thus, is not obvious in view of the Bøgesø references.

The Office implies that the practical advantage of Compound I being a weak inhibitor "is only useful when it is co-administered with drugs that are metabolized by CYP2D6" and thus, "the claims should be limited to such". *See* p. 4 of Final Office Action. Applicants respectfully disagree. Applicants respectfully remind the Office that the compound as a whole - including all of its properties - is patentable if novel, unobvious and useful, regardless of whether any of its advantageous properties are actively engaged or used. By the foregoing, Applicants have shown that Compound I is novel and not obvious, while utility for Compound I is clearly provided in the specification. *See, e.g.,* [0001]-[0009] of the published application.

For the foregoing reasons, claims 34 and 36-44 are not obvious. Applicants respectfully request the § 103(a) rejection be withdrawn.

IV. Provisional nonstatutory double patenting

The Office indicated that the provisional rejections on the ground of nonstatutory obvious-type double patenting over claims of copending USSN 11/816,394 ("the '394 application"), and claims of pending USSN 11/814,403 ("the '403 application") in view of EP'073, would be withdrawn if the present application was deemed allowable. Applicants inform the Office that their previous response to these rejections, which the Office indicated was not a traversal, was an abeyance of any traversal or concession of the rejections until indication of allowable. *See* pp. 4-5 of Final Office Action. These provisional rejections now are moot in view that the '394 application has issued and the '403 application has been expressly abandoned.

V. IDS reference

Applicants thank the Office for indicating duplicate entries and will try to clarify the situation with respect to the Cox reference since the previous attempt was unsuccessful. Applicants have not submitted a full text copy of the Cox reference in any application since it is a 344 page text book ("Preparative Enantioselective Chromatography", Oxford, UK: Blackwell Publishing LTD. 2005) because of its voluminous nature as indicated in the 2/21/08 IDS communication. It was disclosed as such because it was cited without page citation in the present specification with respect to describing that chiral chromatography can be scaled up using suitable technologies, e.g., simulated moving bed technology (SMB), or sub- or supercritical fluid technology. Accordingly, it is not being resubmitted particularly pointing out the pertinent pages

since no particular pages were cited in the specification and the voluminous nature of the reference. Applicants understand that the Office, thus, will not consider the reference under MPEP 609.

VI. Conclusion

Applicants believe the claims are in condition for allowance, and earnestly solicit an early Notice of Allowance. Applicants invite the Examiner to contact the undersigned below if deemed helpful in advancing prosecution of the instant application.

Also, authorization is given to charge the Petition for Extensions of Time and RCE fees, and any other fee, as well as credit any overpayment, to Deposit Account Number 50-3201.

Respectfully submitted,

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